

DEC 1 9 2000

K002156

510(k) SUMMARY

**Osborn Group, Inc
Appraise Urine Microalbumin Collection Kit**

July 3, 2000

Submitter Information:

Osborn Group, Inc.
19401 West 117th Street
Olathe, Kansas 66062

Submitter's Name: Gilbert P. Bourk III
Phone: (913) 390-7146

Device Name:

Osborn Group, Inc. Appraise Urine Microalbumin Collection Kit

Common Name: Urine collection kit

Classification Name: Specimen container

Predicate Device Equivalence:

Substantial equivalence is claimed to the Osborn Group, Inc. HemoChek Urine Collection Kit and the HemoChek-A1c Sample Collection Kit, cleared for commercial distribution per K991800 and K990899, respectively.

Device Description:

Indications for Use:

The Appraise Urine Microalbumin Collection Kit is for over-the-counter sale for use in collecting a urine specimen and preserving the specimen for laboratory testing for kidney disfunction in diabetics. Abnormal results should be reported to your physician.

The device consists of the following:

- A collector pad holder/handle with a collector pad and a protective cover over the pad, contained in a sealed "peel-apart" plastic envelope. The collector pad holder/ handle itself consists of two parts, a collector pad holder and a collector pad slider. The collector pad is held in the holder/handle by a pin in the slider that fits into a hole in the collector pad, and by the holder, which keeps the pad from falling off the pin. The slider has a round indicator port in it. A blue color appears in this indicator port when a sufficient amount of urine has been collected.

- A peel-open pouch that contains the collector pad holder/handle with the collector pad.
- A Collection Tube with a screw-on lid, containing preservative fluid.
- An inner package that contains the above three items.
- An Instruction Card Insert.
- A Patient Card printed on both sides, affixed to the Instruction Card Insert by means of glue dots. In the case of kits coming from Managed Care facilities, the patient information will be on the front of the card. However, if the information has changed, or if the patient has purchased the kit, then the back side of the card is filled in by the patient.
- A set of instructions.
- A plastic zip lock bag into which the Collection Tube is placed after the sample has been taken.
- A prepaid mailer into which the zip lock bag is placed after the sample has been taken..
- A polyethylene mailing envelope with a see-through window which contains all of the above items and is used to mail the Appraise Urine Microalbumin Collection Kit to the patient.

Intended Use:

The Appraise Urine Microalbumin Collection Kit is for over-the-counter sale for use in collecting a urine specimen and preserving the specimen for laboratory testing for kidney disfunction in diabetics. Abnormal results should be reported to your physician.

Comparison of Technological Characteristics:

The Appraise Urine Microalbumin Collection Kit is very similar to the predicate device, the HemoChek Urine Collection Kit, except for the labeling.

Summary of Device Testing:

Because the device is virtually physically identical to the predicate device, the accuracy and stability testing conducted on the primary predicate device is considered to be adequate to demonstrate safety and effectiveness, and thus no new testing was conducted.

A consumer study was conducted to determine the acceptability of the kit and its labeling. Persons who used the kit found it easy to use.

Conclusions:

Based on the above, we have concluded that the Appraise Urine Microalbumin Collection Kit is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 19 2000

Mr. Gilbert P. Bourk III
Senior Vice President and General Counsel
Osborn Group, Inc.
14901 West 117th Street
Olathe, Kansas 66062

Re: K002156
Device Name: Appraise Urine Microalbumin Collection Kit
Regulatory Class: II
Product Code: CGX
Regulatory Class: I
Product Code: JIQ
Dated: November 10, 2000
Received: November 13, 2000

Dear Mr. Bourk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

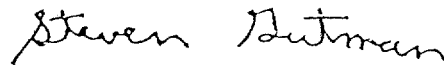
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by-reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Steven Gutman". The signature is fluid and cursive, with the first name "Steven" and last name "Gutman" clearly distinguishable.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name:

Appraise Urine Microalbumin Collection Kit

Indications for Use:

The Appraise Urine Microalbumin Collection Kit is for over-the-counter sale for use in collecting a urine specimen and preserving the specimen for laboratory testing of albumin and creatinine for kidney disfunction in diabetics. Results should be reported to your physician.

✓ OTC

- Rx

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002156